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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,898	03/29/2004	Kazuhiro Ohkouchi	2004_0494	1097
513 7590 12/19/2006 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER VENKAT, JYOTHSNA A	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/19/2006	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,898	<b>Applicant(s)</b> OHKOUCHI ET AL.	
	<b>Examiner</b> JYOTHSNA A. VENKAT Ph. D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12, 13 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-13 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Receipt is acknowledged of amendment and declaration filed under 1.132 filed on 9/19/06. Claims 12-13 are pending in the application and the status of the application is as follows:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 90/46215 ('215).

*The instant application is claiming a quickly disintegrating solid preparation comprising:*

*a. An active ingredient*

*b. Sugar alcohol or saccharide with a mean particle diameter of 30-300 microns*

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*c. Disintegrating agent (carmellose calcium, carboxymethylstarch sodium, croscarmellose sodium or crosspovidone)*

*d. Cellulose compound (crystalline cellulose, powder cellulose, low substituted hydroxy propyl cellulose or carmellose)*

WO '218 teaches all the claimed ingredients in rapidly dissolving dosage form. See the abstract, see pages 4-5, see pages 7-9 for the active ingredients, and see page 17, lines 13-26 for claimed b. The mean particle taught by the document is within the claimed range. See paragraph bridging pages 17-18 for the various saccharide or sugar alcohols. See page 25 for wicking agent. Some of the agents are the species claimed under c as well as d. See the same page, lines 13-20 for povidone of claimed d. See examples and see specially where the document teaches using both c and d into the compositions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare rapidly dosage forms using all the ingredients of WO document. One of ordinary skill in the art would have reasonable expectation of success that the claimed dosage form with ingredients would also dissolve rapidly since using ingredient c helps in transport moisture into the dosage form, and the use of ingredient b helps in the production of a hard, non-friable, directly compressible and rapidly dissolvable in-mouth dosage form. Absent a showing the criticality of the claimed range of the sugar alcohols, the claims are rendered prima facie obvious over WO document.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 90/46215 ('215) as applied to claims 12-13 above, and further in view of U. S. Patent 6,923,988 ('988).

WO as applied above. The difference is WO document does not teach the claimed active ingredients. However patent '988 teaches solid carriers for improved delivery of active ingredients in pharmaceutical compositions. See the abstract, see col.s 4-8 for the active ingredients, see claim 29 for the claimed pioglitazone. Accordingly, it would have been obvious to one of ordinary skill in the art to use the claimed pioglitazone of patent into the compositions of WO document. One of ordinary skill in the art would be motivated to use the specific active ingredient with the reasonable expectation of success that the compositions with the specific active ingredient would dissolve rapidly and also increase the bioavailability of the active ingredient. This is a prima facie case of obviousness.

***Response to Amendment***

The declaration under 37 CFR 1.132 filed 9/19/06 is insufficient to overcome the rejection of claims 12-13 based upon WO 90/46215 ('215) as set forth in the last Office action because:

1. Examples 2-4 recite only particle size of 45 microns (see page 2 of the declaration)
2. Examples 2-4 do not recite particle size of 130 microns . This is also true for example 8. There is no particle diameter of 130 microns in example 8 (see page 2 of the declaration)
3. Examples 5-7 do not recite particle size of 130 microns (see page 2 of the declaration)

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4. Examples 10-12 and 14-15 recite larger particle size and the particle size mentioned at page 2 of the declaration correspond to sugar alcohols that are pulverized. *None of the claims recite that the sugar alcohols are pulverized.*
5. All the examples are specific to active ingredient. Claims 12-13 do not recite active ingredient.
6. Therefore the results are not commensurate with the scope of particle diameter of the sugar alcohols.

Note that there is overlap with the particle diameter claimed and the particle diameter disclosed in the WO document with respect to sugar alcohols. Therefore WO document is also expected to give the solid preparations meeting the criteria of fluidity during tableting, binding property, adhesion to punch, hardness and intra oral disintegration time.

In view of the above reasons, the declaration is ineffective.

The declaration is ineffective therefore rejection of claim under 35 U.S.C. 103(a) as being unpatentable over WO 90/46215 ('215) as applied to claims 12-13 above, and further in view of U. S. Patent 6,923,988 ('988) is also maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

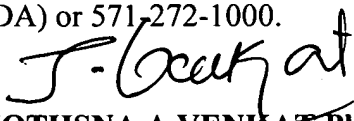
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**JYOTHSNA A VENKAT Ph. D**  
**Primary Examiner**  
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